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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/679,710

10/03/2003

Arthur M. Krieg

C1039.70074US00

9983

7590 02/13/2007  
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EXAMINER

HORNING, MICHELLE S

ART UNIT

PAPER NUMBER

1648

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

02/13/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/679,710	<b>Applicant(s)</b> KRIEG ET AL.	
	<b>Examiner</b> Michelle Horning	<b>Art Unit</b> 1648	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12/26/2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 45-47, 52 and 94-100 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 45-47, 52 AND 94-100 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

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### **DETAILED ACTION**

This office action is responsive to communication filed 12/26/2006. The status of the claims is as follows: claims 1-44, 48-51 and 53-93 have been cancelled and claims 45-47, 52 and 94-100 are under current examination.

Applicant's election without traverse of all claims in the reply filed on 12/26/2006 is acknowledged.

### ***IDS***

No IDS has been submitted.

### ***Claim Rejections***

#### **35 U.S.C. 112, 1<sup>st</sup> paragraph**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Claim 45-47, 52 and 94-100 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.** The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Enablement is considered in view of the *Wands* factors (MPEP 2164.01(a)).

*Nature of the invention.* The claims are drawn to a method of treating or eliminating a tumor or cancer in a subject comprising administering an immunostimulatory nucleic acid molecule (sequence motifs listed in claim 45).

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*State of the prior art.* At the time the invention was made, there was no known cure to cancer.

*Breadth of the claims.* The claims are extremely broad in that they are drawn to the treatment and elimination of tumors and cancers of all types, including malignant haematological diseases, lung cancer, brain tumors, esophageal cancer and ovarian cancer as examples.

*Working examples.* The working examples in the specification demonstrate the effects of ODNs on B cells isolated from mice spleens, including production of IgM and RNA synthesis, and the *in vivo* effects of CpG in mice following injection. No working example of the claimed method is provided.

*Guidance in the specification.* The specification provides no guidance regarding a single method that treats or eliminates tumors and cancer of all types in a subject. There are no figures or actual data demonstrating the claimed method.

*Predictability in the art.* The physiological art in general is acknowledged to be unpredictable (MPEP 2164.03). Bodey et al (2000) states that "malignant tumors undergo constant microevolution" with regard to the immunophenotype of cells (page 2673). Following neoplastic transformation, there are further alterations in the physiology of cells contained within the cytoplasm and nucleus, thus making molecules associated with such changes less than ideal targets for immunotherapy (page 2666). Thus, given the known "constant microevolution" of tumor cells, there is no way one could predict which immunostimulatory nucleic acid molecule would lead to the desired

effect (elimination of cancer or tumors) or what changes in activity might result by the tumor cells.

*Amount of experimentation necessary.* Bodey et al (2000) review the state of cancer treatment. This reference recites the following: "The use of cancer vaccines seems, at present, destined to remain limited to their employment as adjuvants to both traditional therapies and in the management of minimal residual disease following surgical resection of the primary cancer mass" (see Abstract). This reference further recites: "active immunotherapy has not yet become an established modality of anticancer therapy" (page 2665). Thus, it will require years of further research to develop a successful therapy against cancer as well as understand the fundamental biology of tumors and cancers.

For the reasons discussed above, it would require undue experimentation of one skilled in the art to use the claimed methods.

### **CONCLUSION**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle Horning whose telephone number is 571-272-9036. The examiner can normally be reached on Monday-Friday, 8:30 am to 5 pm.

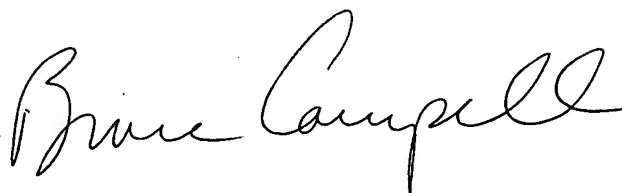
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 570-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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unpublished application is available through Private PAIR only. For more information about PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Michelle Horning  
Patent Examiner



**BRUCE R. CAMPELL, Ph.D.  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600**